

A COMPARISON OF KNEE SAGITTAL PLANE BIOMECHANICS DURING STAIR
ASCENT BETWEEN INDIVIDUALS UNDERGOING TOTAL KNEE OR
UNICOMPARTMENTAL KNEE ARTHROPLASTY AND HEALTHY CONTROLS

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LIST OF ABBREVIATIONS

Total Knee Arthroplasty.....	TKA
Unilateral Knee Arthroplasty.....	UKA
Osteoarthritis.....	OA
Ground Reaction Force.....	GRF
Peak Knee Flexion Angle.....	KFA
Peak Knee Flexion Moment.....	KFM
Peak Knee Extension Power.....	KEP

INTRODUCTION

Osteoarthritis (OA) is the most common form of arthritis in the United States and typically involves the knee joint, which can greatly affect stair negotiation^{1,2}. Those with knee OA may experience decreases in step, stride length, and walking velocity, as well as increased step width and more time in double limb support while walking^{3,4}. Those suffering from OA also experience decreased knee extensor strength which leads to decreases in peak knee flexion angle (PKFA), peak knee flexion moment (PKFM) and vertical ground reaction force (vGRF)⁴. Knee extensor weakness can make stair ascent difficult as the ability to ascend stairs is directly related to the function of knee extensor musculature⁵. Increases in trunk flexion can be observed to accommodate for a lack of quadriceps activation with stair ascent⁵. Stair negotiation is an important functional activity to biomechanically assess because it accounts for 10% of fall-related deaths in the elderly^{6,7}.

A total knee arthroplasty (TKA) surgical intervention is performed in patients with moderate to severe knee OA^{8,9}. Total Knee Arthroplasty has been associated with relatively high levels of self-reported patient dissatisfaction with post-operative function, despite being a successful orthopedic surgical procedure that reduces pain and improves function^{10,11}. Patients demonstrate decreased knee extensor strength compared to controls following surgery, which directly effects the ability to perform activities of daily living, like ascending stairs^{12,13}.

Unicompartmental Knee Arthroplasty (UKA) is an alternative surgical treatment for OA and is used to treat OA limited to the medial or lateral compartment of the knee¹⁴. Younger patients are being recommended for the UKA procedure before medial OA progresses to further compartments^{15,16}. Those receiving the minimally invasive UKA have demonstrated improved early ROM, normal knee extensor muscle function, shorter hospital stays and improved functional scores, when compared to TKA patients¹⁷⁻¹⁹. Unilateral knee arthroplasty patients

experience higher function following surgery as indicated by quicker return to activities of daily living²⁰.

Motion analysis techniques provide precise measurements of knee biomechanics and insight into the specific deficits faced by TKA and UKA patients. While limited studies have examined the biomechanics of level walking gait in TKA and UKA patients^{9,17,21-23}, fewer studies have analyzed kinematic and kinetic variables during stair ascent in knee arthroplasty patients^{13,18,24,25}. There is a need for longitudinal studies, as the majority of research studies comparing UKA and TKA surgical outcomes are cross sectional in design^{9,10,16,21,22,25,26}.

Therefore, the purpose of this research is to evaluate knee kinematic and kinetic variables in UKA, TKA, and healthy control participants during stair ascent prior to, and at six-weeks, three-months, six-months and one-year following surgery. It is hypothesized that UKA patients will exhibit kinematic and kinetic profiles that are more similar post-operatively to healthy controls than patients who have undergone TKA.

METHODOLOGY

Research Design

A longitudinal design was utilized to investigate the effectiveness of Unicompartamental Knee Arthroplasty (UKA) implant design when compared to Total Knee Arthroplasty (TKA) implants and healthy controls. Biomechanical assessment of osteoarthritic (OA) patients during stair negotiation occurred within one week prior to surgery and post-surgery at 6-weeks, 3-months, 6-months and 1-year. Healthy control participants completed a single biomechanical assessment and were used for comparison of biomechanical variables of interest to knee arthroplasty patients. Biomechanical variables collected included, peak knee extensor strength (KES), time to ascend stairs, peak knee flexion angle (KFA), peak knee flexion moment (KFM), vertical ground reaction force (vGRF), and peak knee extension power (KEP).

Participants

Inclusion criteria for all arthroplasty patients consisted of: under 75 years of age, no previous history of lower extremity fracture, osteotomy, or joint replacement, undergoing an unilateral or bilateral UKA or TKA for the treatment of osteoarthritis, and physically able to walk without an aid. Total Knee Arthroplasty patients were screened for inclusion in this study and randomly assigned to receive either a single radius (SR) (GetAroundKnee™, Stryker Orthopedics, Mahwah,NJ) or a multi-radius (MR) implant (Balanced Knee® System, Ortho Development Corporation, Draper, UT) design. Both TKA implants received patellar resurfacing. All UKA patients screened for inclusion received an Oxford® Partial Knee Implant (Zimmer Biomet Orthopedics, Warsaw, IN). All TKA and UKA surgeries were performed by

the same board certified orthopedic surgeon. Data were collected on healthy control participants in the same manner on the right limb only at a single data collection. Inclusionary criteria for the controls included: between 55-75 years of age with no previous history of heart condition, balance or fainting disorders, Parkinson's Disease, diagnosed neurological disorders, diabetes mellitus, rheumatoid arthritis, osteoarthritis, surgery to the hip, knee or ankle, or injury or severe knee pain in the last six months.

Prior to study enrollment, all participants signed informed consent forms approved by the University Human Studies Program. Once consent was gained, participants received an ID number that was used for all data collection sessions and paperwork. All participant data was secured in a filing cabinet in a locked office. All adverse events, such as injury during testing sessions, was monitored and reported to the Institutional Review Board in accordance to the reporting criteria.

Procedures

All biomechanical data collections were conducted at the University of Hawai'i Gait Laboratory. Upon arrival at each visit, participants answered two questions consisting of: 1) "how does your knee affect your ability to rise from a chair?" (1-"because of my knee I cannot rise from a chair" to 4-"my knee does not affect my ability to rise from a chair") and 2) "are you satisfied with your replacement?" ("yes" or "no"). Control participants completed a health questionnaire to determine eligibility to participate as a control subject in this study. Following completion of the surveys, participant's height was collected using a wall-mounted stadiometer (Model 67032, Seca Telescopic Stadiometer, Country Technology, Inc., Gays Mills, WI, USA) and body mass was collected using a Detecto certifier scale (Webb City Mo, USA). Shank lengths were recorded as the distance measured from the lateral knee joint line to the distal

lateral malleolus; 80% of shank length was calculated and marked. These markings serve as location points for placement of the hand-held dynamometer during knee extensor strength testing, to allow for consistent placement of the dynamometer relative to each patient.

Twenty-nine reflective markers were placed bilaterally over: anterior superior iliac spines, posterior superior iliac spines, medial and lateral femoral condyles, medial and lateral malleoli, calcanei, base and head of the fifth metatarsals, head of the first and second metatarsals and acromioclavicular joints. Rigid marker arrays were placed bilaterally on lateral thighs and shanks. Single reflective markers were placed over: xyphoid process, superior aspect of manubrium at the jugular notch, vertebral spinous process of cervical seven, thoracic vertebral spinous process of thoracic ten and the inferior angle of the right scapula. Markers on the medial femoral epicondyle, medial malleolus and head of the first metatarsal were used for calibration purposes during a static trial only and were removed for stair trials.

A three-step staircase, with dimensions of an 18cm step rise, 46cm step width and 28cm step tread was used for assessing stair negotiation. Each participant began walking at a self-selected velocity two meters before ascending the stairs using a reciprocal foot-fall pattern with the surgical limb contacting the ground and second-step. A handrail was provided for safety but patients were instructed not to use it unless balance was compromised. If the handrail was used, the trial was discarded. A member of the research team was positioned at the bottom of the stairs at all times to provide further assistance if needed. During stair negotiation trials, marker positions were collected using a Vicon Nexus motion capture system (Vicon, Inc., Centennial, CO). Two force plates (Advanced Mechanical Technology Incorporated, Boston, MA), one embedded flush with the floor and one instrumented within the second step of the stairs, were used to collect kinetic data on the surgical limb. Kinematic data was collected at 240 Hz and

time synchronized with kinematic data collected at 960 Hz. A low-pass Butterworth filter was used to filter kinematic data and kinetic data used for calculation of external joint moments at a 10 Hz cut-off frequency and ground reaction force data was filtered using a 50 Hz cut-off frequency. Joint moments were calculated using inverse dynamics based on filtered marker trajectories and kinetic data. All joint moments were reported as external moments and knee flexion values were reported as a positive number. All data were processed using Visual 3D (C-Motion, Inc., Germantown, MD). Due to high intra-subject variability previously reported during stair climbing in the OA population, five successful trials were averaged²⁷.

Following stair ascent trials, knee extensor muscle strength tests were performed bilaterally using a handheld dynamometer (Hoggan Health Industries, West Jordan, UT). Placement of the dynamometer was at the marked 80% length of the shank and was secured in place by a strap to ensure constant resistance. Knee extensor strength was performed with the patient in a recumbent seated position with their knee flexed to 65° and their trunk extended 130° from the surface of the treatment table with their hands placed on the table behind them supporting their trunk in this position. Participants were instructed to build a force over three seconds, holding the maximal force contraction for two seconds. Two trials of a three-second maximal effort isometric knee extension contraction were completed. A third trial was completed if the second trial did not measure within 10% force output of the first trial. Verbal encouragement was given to help elicit maximal force production by the participant during strength testing.

Statistical Analysis

Data normality and homogeneity of variance was assessed using the Shapiro-Wilk (SW) and Levene's Tests, respectively. Multiple general linear model analyses of variance were performed to identify significant differences in dependent biomechanical variables between

controls, TKA and UKA groups. When the assumptions of ANOVA were violated via significant SW or Levene's Test, the Mann-Whitney U Test was used to assess non-parametric data. Frequencies were reported on 'Ability to rise from a chair' and patient satisfaction. All data were analyzed using SPSS Version 22.0 and an alpha level of $P \leq 0.05$ was used to determine statistical significance.

RESULTS

Participant demographics can be found in Table 1. Thirty-three operated knees (UKA n=9; 2 bilateral, TKA n=24; 6 bilateral) were included in the analysis. Separate groups of matched controls were used for comparison to each surgical group. There were no differences between groups for age, height, or weight.

Table 1

ANOVA Results of Participant Demographics

	UKA (n=7)	CON (n=9)	UKA v. CON	UKA vs TKA
	Mean (SD)	Mean (SD)	<i>P</i> -value	<i>P</i> -value
Age (y)	67.2 (3.9)	68.1 (5.2)	0.850	0.159
Height (m)	1.7 (0.1)	1.8 (0.1)	0.432	0.716
Weight (kg)	90.9 (16.0)	92.4 (18.6)	0.813	0.633
	TKA (n=18)	CON (n=24)	TKA v. CON	
	Mean (SD)	Mean (SD)	<i>P</i> -value	
Age (y)	64.9 (5.0)	63.8 (6.9)	0.564	
Height (m)	1.7 (.1)	1.7 (.1)	0.462	
Weight (kg)	81.7 (16.0)	80.6 (15.8)	0.820	

UKA, Unilateral Knee Arthroplasty; TKA, Total Knee Arthroplasty.

CON, Control; SD, Standard Deviation.

$P \leq 0.05$ significance; y, years; m, meters; kg, kilograms.

The TKA versus controls means, SD, confidence intervals, and *P* values for all dependent variables are presented in Table 2. There were significant differences between groups at each time point for strength, time to ascent, and several kinetics. The TKA group was 23% weaker than controls at the pre-operative time, worsened to 40% weaker 6-weeks post-operatively, 31% weaker 3-months post-operatively, 24% weaker 6-months post-operatively, and remained 20% weaker at the 1-year post-operative session. At the pre-operative and 6-week post-operative assessment, the TKA were 31% slower than controls at ascending stairs, 20% slower at 3-

months, and 17% slower at 6-months and 1-year. The TKA were 5-9% lower GRF compared to controls at each time point. The TKA group demonstrated 45% lower KFM than controls pre-operatively. This deficit compared to controls was 64% 6-weeks post-operatively, 55% 3-months post-operatively, 45% 6-months post-operatively, and remained 37% lower 1-year post-operatively. Knee extension power was 51% lower than controls pre-operatively, and 67%, 53%, 54%, 51% post-operatively at the 6-week, 3-month, 6-months, and 1-year time points, respectively. There were no significant differences between TKA and controls in KFA at any time point.

Table 2
Descriptive Data for Dependent Measures Over Time For Control and Total Knee Arthroplasty Groups

	Groups	Pre-operatively				6-Weeks			
		N	Mean (SD)	95% CI	P	N	Mean (SD)	95% CI	P
KES (lbs.)	CON	23	86.6 (23.9)	76.3-96.9	0.01^{a,d}	23	86.6 (23.9)	76.3-96.9	0.01^{a,d}
	TKA	24	67.1 (28.9)	54.9-79.3		20	51.5 (24.7)	40.0-63.1	
Time to Ascent (s)	CON	24	2.0 (0.2)	1.9-2.1	0.01^{b,d}	24	2.0 (0.2)	1.9-2.1	0.01^{b,d}
	TKA	23	2.9 (1.0)	2.5-3.3		16	2.9 (1.0)	2.4-3.5	
KFA (°)	CON	24	67.3 (5.0)	65.2-69.4	0.31 ^b	24	67.3 (5.0)	65.2-69.4	0.07 ^b
	TKA	23	69.3 (6.7)	66.4-72.2		17	64.8 (6.4)	61.4-68.1	
vGRF (N/kg)	CON	24	11.5 (0.7)	11.2-11.8	0.01^{a,d}	24	11.5 (0.7)	11.2-11.8	0.01^{b,d}
	TKA	23	10.5 (0.7)	10.2-10.8		17	10.5 (0.8)	10.1-10.9	
KFM (Nm/kg)	CON	24	1.1 (0.2)	1.1-1.0	0.01^{a,d}	24	1.1 (0.2)	1.1-1.0	0.01^{a,d}
	TKA	23	0.6 (0.3)	0.7-0.5		17	0.4 (0.2)	0.5-0.3	
KEP (W)	CON	24	55.2 (57.3)	79.4-31.1	0.01^{b,d}	24	55.2 (57.3)	79.4-31.1	0.01^{b,d}
	TKA	23	26.8 (19.6)	35.2-18.3		17	18.3 (11.6)	24.3-12.4	

	Groups	3-Months				6-Months			
		N	Mean (SD)	95% CI	P	N	Mean (SD)	95% CI	P
KES (lbs.)	CON	23	86.6 (23.9)	76.3-96.9	0.01 ^{a,d}	23	86.6 (23.9)	76.3-96.9	0.01 ^{a,d}
	TKA	22	59.4 (18.6)	51.2-67.7		22	65.9 (23.9)	55.3-76.5	
Time to Ascent (s)	CON	24	2.0 (0.2)	1.9-2.1	0.01 ^{b,d}	24	2.0 (0.2)	1.9-2.1	0.01 ^{b,d}
	TKA	21	2.5 (0.4)	2.3-2.7		23	2.4 (0.4)	2.2-2.6	
KFA (°)	CON	24	67.3 (5.0)	65.2-69.4	0.07 ^b	24	67.3 (5.0)	65.2-69.4	0.21 ^b
	TKA	21	66.0 (4.4)	64.0-68.0		23	65.8 (6.1)	63.2-68.5	
vGRF (N/kg)	CON	24	11.5 (0.7)	11.2-11.8	0.01 ^{a,d}	24	11.5 (0.7)	11.2-11.8	0.01 ^{b,d}
	TKA	19	10.6 (0.5)	10.4-10.8		23	10.9 (0.6)	10.6-11.2	
KFM (Nm/kg)	CON	24	1.1 (0.2)	1.1-1.0	0.01 ^{a,d}	24	1.1 (0.2)	1.1-1.0	0.01 ^{b,d}
	TKA	19	0.5 (0.2)	0.6-0.4		23	0.6 (0.2)	0.7-0.5	
KEP (W)	CON	24	55.2 (57.3)	79.4-31.1	0.02 ^{b,c}	24	55.2 (57.3)	79.4-31.1	0.01 ^{b,d}
	TKA	19	25.7 (19.8)	35.2-16.2		23	25.6 (20.1)	34.3-17.0	
	Groups	1-year							
		N	Mean (SD)	95% CI	P				
KES (lbs.)	CON	23	86.6 (23.9)	76.3-96.9	0.02 ^{a,c}				
	TKA	20	69.5 (27.2)	56.8-82.2					
Time to Ascent (s)	CON	24	2.0 (0.2)	1.9-2.1	0.01 ^{b,d}				
	TKA	20	2.4 (0.4)	2.2-2.5					
KFA (°)	CON	24	67.3 (5.0)	65.2-69.4	0.81 ^b				
	TKA	20	67.9 (5.3)	65.4-70.4					
vGRF (N/kg)	CON	24	11.5 (0.7)	11.2-11.8	0.01 ^{a,d}				
	TKA	20	10.7 (0.6)	10.4-11.0					
KFM (Nm/kg)	CON	24	1.1 (0.2)	1.1-1.0	0.01 ^{a,d}				
	TKA	20	0.7 (0.2)	0.7-0.6					
KEP (W)	CON	24	55.2 (57.3)	79.4-31.1	0.01 ^{b,d}				
	TKA	20	27.0 (21.6)	37.1-16.9					

CON, Control; TKA, Total Knee Arthroplasty.

KES (lbs.), Knee Extensor Strength pounds; (s), seconds; KFA (°), Peak Knee Flexion Angle degrees.

vGRF (N/kg), Vertical Ground Reaction Force newtons per kilogram.

KFM (Nm/kg), Peak Knee Flexion Moment newton meters per kilogram.

KEP (W), Peak Knee Extension Power watts.

^a=ANOVA, ^b=Mann Whitney, ^c= $P \leq 0.05$, ^d= $P < 0.01$.

The UKA versus controls means, SD, confidence intervals, and *P* values for all dependent variables can be seen in Table 3. The UKA group was 39% slower to ascend the stairs compared to controls pre-operatively, was 28% slower 6-weeks post-operatively, 18%

slower 3-months and 6-months post-operatively, and improved to 14% slower 1-year post-operatively. Peak knee flexion angle was non-significant at every time point except for 1-year post-operatively in which UKA produced 114% more KFA than controls. Vertical ground reaction force was significantly different pre-operatively, with UKA producing 13% less force than controls. The groups were not significantly different by 6-weeks post-operatively, and the UKA mean continued to improve over the course of the study. Peak knee flexion moment was not significantly different pre-operatively though UKA produced a moment 20% less than controls. Significance was found at 6-weeks, 3-months, and 6-months post-operatively in which UKA's produced 42%, 40%, and 30% less moment compared to controls. Though not significant, UKA had a 30% less KFM than controls at the 1-year post-operative collection ($P=0.06$). Significance was found for KEP pre-operatively and 6-weeks post-operatively with UKA producing 68% and 71% less power than controls, respectively. Knee extensor strength was not significantly different across all time points.

Table 3

Descriptive Data for Dependent Measures Over Time for Control and Unilateral Knee Arthroplasty Groups

	Groups	Pre-operatively				6-Weeks			
		N	Mean (SD)	95% CI	<i>P</i>	N	Mean (SD)	95% CI	<i>P</i>
KES (lbs.)	CON	9	80.6 (25.0)	61.4-99.9	0.94 ^a	9	80.6 (25.0)	61.4-99.9	0.44 ^a
	UKA	9	81.9 (37.8)	52.9-110.9		9	70.9 (26.9)	50.2-91.5	
Time to Ascent (s)	CON	9	1.9 (0.2)	1.8-2.0	0.01 ^{b,d}	9	1.9 (0.2)	1.8-2.0	0.01 ^{b,d}
	UKA	8	3.1 (0.6)	2.6-3.6		9	2.6 (0.4)	2.3-2.9	
KFA (°)	CON	9	66.7 (6.1)	62.0-71.4	0.32 ^b	9	66.7 (6.1)	62.0-71.4	0.16 ^b
	UKA	8	65.8 (3.5)	62.9-68.8		9	63.5 (5.7)	59.2-67.9	
vGRF (N/kg)	CON	9	11.7 (0.9)	11.0-12.3	0.01 ^{a,d}	9	11.7 (0.9)	11.0-12.3	0.08 ^a
	UKA	8	10.2 (0.7)	9.6-10.7		9	10.5 (1.7)	9.2-11.8	
KFM (Nm/kg)	CON	9	1.0 (0.2)	1.2-0.9	0.06 ^b	9	1.02 (0.2)	1.2-0.9	0.01 ^{b,d}
	UKA	8	0.8 (0.3)	1.0-0.5		9	0.6 (0.2)	0.7-0.5	
KEP (W)	CON	9	65.1 (58.6)	110.1-20.1	0.04 ^{b,c}	9	65.1 (58.6)	110.1-20.1	0.01 ^{b,d}
	UKA	8	20.8 (12.6)	31.4-10.2		9	18.6 (10.8)	26.9-10.3	

	Groups	3-Months				6-Months			
		N	Mean (SD)	95% CI	<i>P</i>	N	Mean (SD)	95% CI	<i>P</i>
KES (lbs.)	CON	9	80.6 (25.0)	61.4-99.9	0.96 ^b	9	80.6 (25.0)	61.4-99.9	0.80 ^b
	UKA	8	76.2 (26.6)	53.9-98.5		9	86.8 (38.0)	57.6-116.0	
Time to Ascent (s)	CON	9	1.9 (0.2)	1.8-2.0	0.01 ^{b,d}	9	1.9 (0.2)	1.8-2.0	0.01 ^{a,d}
	UKA	9	2.3 (0.1)	2.2-2.4		9	2.3 (0.1)	2.2-2.5	
KFA (°)	CON	9	66.7 (6.1)	62.0-71.4	0.86 ^b	9	66.7 (6.1)	62.0-71.4	0.80 ^b
	UKA	9	68.0 (6.2)	63.2-72.7		9	68.3 (7.3)	62.7-73.9	
vGRF (N/kg)	CON	9	11.7 (0.9)	11.0-12.3	0.10 ^a	9	11.7 (0.9)	11.0-12.3	0.34 ^a
	UKA	9	11.0 (0.7)	10.5-11.6		9	11.3 (0.8)	10.7-11.9	
KFM (Nm/kg)	CON	9	1.0 (0.2)	1.2-0.9	0.01 ^{a,d}	9	1.0 (0.2)	1.2-0.9	0.03 ^{b,c}
	UKA	9	0.6 (0.2)	0.8-0.5		9	0.7 (0.3)	0.9-0.5	
KEP (W)	CON	9	65.1 (58.6)	110.1-20.1	0.05 ^{b,c}	9	65.1 (58.6)	110.1-20.1	0.14 ^b
	UKA	9	25.6 (17.1)	38.8-12.5		9	31.1 (18.0)	45.0-17.2	
	Groups	1-year							
		N	Mean (SD)	95% CI	<i>P</i>				
KES (lbs.)	CON	9	80.6 (25.0)	61.4-99.9	0.55 ^a				
	UKA	9	90.0 (37.8)	60.9-119.0					
Time to Ascent (s)	CON	9	1.9 (0.2)	1.8-2.0	0.01 ^{a,d}				
	UKA	9	2.2 (0.2)	2.1-2.4					
KFA (°)	CON	9	66.7 (6.1)	62.0-71.4	0.01 ^{b,d}				
	UKA	9	75.8 (5.6)	71.5-80.2					
vGRF (N/kg)	CON	9	11.7 (0.9)	11.0-12.3	0.44 ^b				
	UKA	9	11.9 (2.5)	9.9-13.8					
KFM (Nm/kg)	CON	9	1.0 (0.2)	1.2-0.9	0.06 ^b				
	UKA	9	0.7 (0.3)	1.0-0.5					
KEP (W)	CON	9	65.1 (58.6)	110.1-20.1	0.14 ^b				
	UKA	9	30.2 (13.8)	40.9-19.6					

CON, Control; UKA, Unilateral Knee Arthroplasty.

KES (lbs.), Knee Extensor Strength pounds; (s), seconds; KFA (°), Peak Knee Flexion Angle degrees.

vGRF (N/kg), Vertical Ground Reaction Force newtons per kilogram.

KFM (Nm/kg), Peak Knee Flexion Moment newton meters per kilogram.

KEP (W), Peak Knee Extension Power watts.

a=ANOVA, b=Mann Whitney, c= $P \leq 0.05$, d= $P < 0.01$.

The UKA versus TKA means, SD, confidence intervals, and *P* values can be seen in Table 4. The 1-year KFA ($p < 0.01$), 3-month GRF ($p = 0.05$), and 6-week KFM ($p = 0.02$) were all

significantly greater in the UKA group. The TKA group produced 44% less moment 6-weeks post-operatively, and improved to UKA values 1-year post-operatively. There were no significant differences between TKA and UKA in strength, time on stairs, and KEP at any point.

Table 4

Descriptive Data for Dependent Measures Over Time for Unilateral and Total Knee Arthroplasty Groups

	Group	Pre-operatively				6-Weeks			
		N	Mean (SD)	95% CI	P	N	Mean (SD)	95% CI	P
KES (lbs.)	UKA	9	81.9 (37.8)	52.9-110.9	0.24 ^a	9	70.9 (26.9)	50.2-91.5	0.07 ^a
	TKA	24	67.1 (28.9)	54.9-79.3		20	51.5 (24.7)	40.0-63.1	
Time to Ascent (s)	UKA	8	3.1 (0.6)	2.6-3.6	0.24 ^b	9	2.6 (0.4)	2.3-2.9	0.64 ^b
	TKA	23	2.9 (1.0)	2.5-3.3		16	2.9 (1.0)	2.4-3.5	
KFA (°)	UKA	8	65.8 (3.5)	62.9-68.8	0.07 ^b	9	63.5 (5.7)	59.2-67.9	0.64 ^a
	TKA	23	69.3 (6.7)	66.4-72.2		17	64.8 (6.4)	61.4-68.1	
vGRF (N/kg)	UKA	8	10.2 (0.7)	9.6-10.7	0.20 ^a	9	10.5 (1.7)	9.2-11.8	0.53 ^b
	TKA	23	10.5 (0.7)	10.2-10.8		17	10.5 (0.8)	10.1-10.9	
KFM (Nm/kg)	UKA	8	0.8 (0.3)	1.0-0.5	0.26 ^b	9	0.6 (0.2)	0.7-0.5	0.02^b
	TKA	23	0.6 (0.3)	0.7-0.5		17	0.4 (0.2)	0.5-0.3	
KEP (W)	UKA	8	20.8 (12.6)	31.4-10.2	0.44 ^b	9	18.6 (10.8)	26.9-10.3	0.75 ^b
	TKA	23	26.8 (19.6)	35.2-18.3		17	18.3 (11.6)	24.3-12.4	
	Groups	3-Months				6-Months			
		N	Mean (SD)	95% CI	P	N	Mean (SD)	95% CI	P
KES (lbs.)	UKA	8	76.2 (26.6)	53.9-98.5	0.20 ^b	9	86.8 (38.0)	57.6-116.0	0.15 ^b
	TKA	22	59.4 (18.6)	51.2-67.7		22	65.9 (23.9)	55.3-76.5	
Time to Ascent (s)	UKA	9	2.3 (0.1)	2.2-2.4	0.13 ^b	9	2.3 (0.1)	2.2-2.5	0.43 ^b
	TKA	21	2.5 (0.4)	2.3-2.7		23	2.4 (0.4)	2.2-2.6	
KFA (°)	UKA	9	68.0 (6.2)	63.2-72.7	0.33 ^a	9	68.3 (7.3)	62.7-73.9	0.33 ^a
	TKA	21	66.0 (4.4)	64.0-68.0		23	65.8 (6.1)	63.2-68.5	
vGRF (N/kg)	UKA	9	11.0 (0.7)	10.5-11.6	0.05^{a,c}	9	11.3 (0.8)	10.7-11.9	0.48 ^b
	TKA	19	10.6 (0.5)	10.4-10.8		23	10.9 (0.6)	10.6-11.2	
KFM (Nm/kg)	UKA	9	0.6 (0.2)	0.8-0.5	0.06 ^a	9	0.7 (0.3)	0.9-0.5	0.39 ^b
	TKA	20	0.5 (0.2)	0.6-0.4		23	0.6 (0.2)	0.7-0.5	
KEP (W)	UKA	9	25.6 (17.1)	38.8-12.5	0.89 ^b	9	31.1 (18.0)	45.0-17.2	0.17 ^b
	TKA	19	25.7 (19.8)	35.2-16.2		23	25.6 (20.1)	34.3-17.0	

	Groups	1-year			
		N	Mean (SD)	95% CI	P
KES (lbs.)	UKA	9	90.0 (37.8)	60.9-119.0	0.11 ^a
	TKA	20	69.5 (27.2)	56.8-82.2	
Time to Ascent (s)	UKA	9	2.2 (0.2)	2.1-2.4	0.36 ^a
	TKA	20	2.4 (0.4)	2.2-2.5	
KFA (°)	UKA	9	75.8 (5.6)	71.5-80.2	0.01 ^{a,d}
	TKA	20	67.9 (5.3)	65.4-70.4	
vGRF (N/kg)	UKA	9	11.9 (2.5)	9.9-13.8	0.13 ^b
	TKA	20	10.7 (0.6)	10.4-11.0	
KFM (Nm/kg)	UKA	9	0.7 (0.3)	1.0-0.5	0.95 ^b
	TKA	20	0.7 (0.2)	0.7-0.6	
KEP (W)	UKA	9	30.2 (13.8)	40.9-19.6	0.32 ^b
	TKA	20	27.0 (21.6)	37.1-16.9	

UKA, Unilateral Knee Arthroplasty; TKA, Total Knee Arthroplasty.

KES (lbs.), Knee Extensor Strength pounds; (s), seconds; KFA (°), Peak Knee Flexion Angle degrees.

vGRF (N/kg), Vertical Ground Reaction Force newtons per kilogram.

KFM (Nm/kg), Peak Knee Flexion Moment newton meters per kilogram.

KEP (W), Peak Knee Extension Power watts.

a=ANOVA, b=Mann Whitney, c= $P \leq 0.05$, d= $P < 0.01$.

Patient satisfaction was reported at all data collection time points for UKA and TKA groups and is shown in Table 5. One hundred percent of UKA patients were satisfied with their knee implants across all data collection time points. Total knee arthroplasty patients were 67%, 89%, 83%, and 89% satisfied at the 6-week, 3-month, 6-month, and 1-year post-operative appointments, respectfully. Patients were asked “How does your knee affect your ability to rise from a chair?” From pre-operative to 1-year post-operative time point, TKA patients had more patients report a “4” compared to UKA patients.

Table 5**Activity Assessment Survey**

	Pre-op		6-Week		3-Month		6-Month		1-Year	
	UKA (N=7)	TKA (N=18)	UKA (N=7)	TKA (N=14)	UKA (N=7)	TKA (N=17)	UKA (N=7)	TKA (N=17)	UKA (N=7)	TKA (N=16)
Patient Satisfaction	n/a	n/a	100%	67%	100%	89%	100%	83%	100%	89%
Chair Question										
"4"	86%	12%	14%	36%	86%	41%	86%	65%	72%	94%
"3"	0%	44%	72%	57%	0%	3%	0%	24%	14%	0%
"2"	14%	44%	14%	7%	14%	6%	14%	11%	14%	6%
"1"	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Missed				22%		5%		5%		11%

"4", My knee does not affect my ability to rise from a chair.

"3", I have pain when rising from the seated position, but it does not affect my ability to rise.

"2", Because of my knee, I can only rise from a chair if I use my hands and arms to assist.

"1", Because of my knee I cannot rise from a chair.

DISCUSSION

The main finding of this study was that the UKA group was more similar to their matched controls than the TKA were to their controls post-operatively, supporting previous research^{24,25}. The TKA group was only able to achieve a similar knee flexion angle at the study's conclusion, but had worse strength, biomechanics, and ability to ascend stairs compared to controls. Conversely, UKA were only slower in stair ascent by the study's conclusion and had improved their strength and biomechanics compared to their controls.

Walking velocity in patients with OA is decreased when compared to healthy controls^{3,4}. Unilateral patients are able to increase walking speed at a better rate than TKA patients²³. The current study showed that patients with OA ascend stairs at a slower rate than healthy controls because both the UKA and TKA groups ascended at a slower rate. Neither UKA or TKA groups were able to return to control time to ascend on stairs at the 1-year time point.

Ability to ascend stairs served as a major component to this study, as stair negotiation is the number one cause of fall related deaths in elderly^{6,7}. Previous research found that patients with severe OA have lower knee flexion moments and angles than healthy controls during stairs, which leads to a quad avoidance gait^{3,5,28}. This movement pattern was seen similarly in this study, in which TKA patients had a smaller KFM compared to the controls ($p<0.01$) and the UKA ($p=0.06$) groups. The TKA group had 25% lower KFM compared to the UKA, though this finding was not significant ($p=0.26$). Adequate knee extensor strength aids in proper quadriceps function during stair ascent. Pre-operatively TKA had significantly less strength compared to controls. At the 1-year collection patients that underwent the TKA procedure had less strength than the UKA patients.

Inadequate speed, KFA and decreased vGRF leads to a decreased moment and lack of efficiency on stairs. Neither UKA or TKA groups were able to return to a KFM of their controls 1-yr post-operatively. This can be attributed to the fact that peak vGRF and KFA do not occur simultaneously. At 1-year KFA returned to control values for TKA, but vGRF did not, which accounted for the decreased KFM. At 1-year the UKA group exceeded the control groups KFA by $9.1 \pm 0.5^\circ$, and vGRF returned to control values.

Neither UKA or TKA groups were able to produce KEP similar to their matched control groups throughout all collection time points. Knee extension power factors in the velocity that the moment is occurring and the angular velocity occurring at the knee joint through concentric motion. Both surgical groups took longer to ascend the stairs than their controls, which could attribute to decreased velocity of the knee moments. Additionally, TKA patients received patellar resurfacing, whereas UKA patients did not. Patellar resurfacing potentially could have affected the knee extensor mechanism for the TKA patients causing a reduction in their function post-operatively.

The current study supported the hypothesis that UKA patients make a quicker return than TKA patients. At 3-months post-op, UKA matched controls KFA ($68.0^\circ \pm 6.2$, $66.7^\circ \pm 6.1$), whereas it took TKA patients 1-year to match their controls KFA ($67.9^\circ \pm 5.3$, $67.3^\circ \pm 5.0$). Similarly at 6-months post-op, UKA exceeded KES values of the controls ($86.8 \pm 38.0 \text{ Nm} \cdot \text{kg}^{-1}$, $80.6 \pm \text{Nm} \cdot \text{kg}^{-1}$, $P=0.80$), and at 1-year TKA did not reach control KES values (TKA= $69.5 \pm 27.2 \text{ Nm} \cdot \text{kg}^{-1}$, Con= $86.6 \pm 23.9 \text{ Nm} \cdot \text{kg}^{-1}$, $P<0.02$). Similarly, at 3-months UKA returned to control vGRF values, and continued to improve to the 1-year time point, whereas TKA patients did not reach control vGRF values at the 1-year time point.

Limitations for this study included a small sample size, study attrition, lack of standardized rehabilitation protocols, and possible selection bias. A larger sample size of both UKA and TKA participants would yield more accurate results for significance in the study. Having a small sample size for UKA compared to TKA may have affected the power analysis for ANOVA and Mann-Whitney analysis. Participants dropped out of the collection at different post-operative collections affecting the sample size across several comparisons. It was not feasible to control all aspects of the rehabilitation programs, as duration and type for each participant was individualized and varied based on them attending clinics of convenience. This may have affected patient's recovery and function with ascending stairs. Total knee arthroplasty patients either received a single- or multi-radius implant at the discretion of the Board Certified Orthopedic surgeon with patellar resurfacing. The UKA group did not receive patellar resurfacing. Patellar resurfacing may have altered the proprioceptive feedback and neuromuscular control within the TKA group causing delayed recovery times compared to UKA patients. Controlling the rehabilitation programs as well as the type of surgical implant would aid in more accuracy of study results.

Conclusion

The results of the current study show the effectiveness of the UKA implant in improving patient function during stair ascent, when compared to TKA patients, particularly in the early stages following surgery. Patients undergoing UKA demonstrated similar biomechanical outcomes to a healthy control population at one-year post-surgery whereas significant differences were still present between TKA patients and controls at this time point. Significant improvements in strength, knee flexion angle, ground reaction force and knee flexion moment were seen in UKA patients with some of these values exceeding that of the control group. This

study demonstrates the deficits that are still seen in TKA patients up to 1-year post-operatively. Total knee arthroplasty patients showed decreased KES and GRF, and increased time to ascend stairs, when compared to their control group. These results indicate that UKA patients may be able to return to ADL's and physical activity with similar function to a healthy control group at a quicker rate. Surgeons treating patients with OA should favor a UKA procedure over a TKA procedure when possible.

REVIEW OF LITERATURE

Knee Osteoarthritis

Osteoarthritis (OA) affects about 27 million Americans with it greatly affecting the knee joint²⁹. As OA progresses from moderate to severe, knee flexion angle decreases showing the importance of early management of OA²⁹. Compensations and abnormalities can be seen with level walking⁴ and stair ascent^{3,30}. Those with OA attempt to reduce the knee extensor moment to decrease the subsequent joint loading that occurs at the knee during stair ascent^{3,29}. Studies used patient matched controls, and radiographs to determine the severity of OA^{3,5,30}. Researchers found that changes occur in gait to accommodate for decreased knee flexion at stance and throughout the swing phase^{5,30}.

People with knee OA often experience abnormalities and compensations with gait on flat ground and stair negotiation. Hicks-Little et al.³ established spatial and temporal gait parameters that exist between 18 patients (11 men, 60 ± 10 years) with early stage OA to 18 age and gender matched controls in stair ascent. Patients completed the Western Ontario McMaster (WOMAC) osteoarthritis index to assess pain, joint stiffness, and function in individuals with knee OA, as well as radiographic confirmation of unilateral knee OA. Univariate F tests were used for analysis. Patients with knee OA experienced less step length, greater step width, less stride length, less total velocity, less time in single support, more time in double support, greater total time in support, and less total time in swing phase when compared to controls. A component to the previous Hicks-Little research examined the effects of knee OA on hip, knee, and ankle joint kinematics variables during stair ascent and descent³⁰. Those with knee OA experienced smaller PKFA during swing and experienced PKFA later in the support phase of gait than controls.

They concluded that stair climbing disabilities need to be approached in rehabilitation programs for OA patients so limitations do not continue.

Chen et al.⁴ investigated stride characteristics and sagittal ground reaction forces in females of differing age and osteoarthritic knees. Twenty controls (21.7 ± 4.5 years), 15 elderly (63.5 ± 11.3 years), and 20 bilateral OA knees (65.5 ± 9.3 years) completed walking trials with Vicon Motion analysis. Univariate repeated measures analysis of variance and post hoc Tukey analysis were used for statistical analysis. Compared to controls, elderly had slower walking velocity, lower cadence and longer stride time. Additionally, when compared to controls and elderly, the OA individuals had slower walking velocity, lower cadence and longer stride time. Knowing these discrepancies in gait, rehabilitation can be targeted to address these dysfunctions in elderly and OA knees.

Quadriceps muscle activation accounts for the ability to ascend stairs. Patterns of movement are likely to be adopted by OA patients during stair ascent to compensate for the loss of quadriceps function. Asay et al.⁵ determined if there is a distinctive characteristic in the pattern of movement during stair climbing in 23 patients (15 women, 61.8 ± 7.3 years) with tibiofemoral knee osteoarthritis (OA) and 20 controls (11 women, 53.7 ± 12 years). A two-step stair system embedded with a force plate, reflective markers, and a 7-camera system were used for this study. Analysis of variance, Bonferroni adjustments, and repeated measures paired student's t-test, were used for statistical analysis. Patients with severe OA had lower PKFM than controls at 3.3 ± 1.22 and 5.1 ± 1.2 , respectively. Knee flexion angles were also lower in OA patients than controls at $60.5 \pm 5.1^\circ$ and $63.7 \pm 4.7^\circ$, respectively. Those with greater peak trunk flexion angles had smaller PKFM. Additionally, PKFM was lower on the affected side than the contralateral limb in OA patients.

Osteoarthritis is a debilitating condition that is growing in America. It is through proper rehabilitation measures that gait abnormalities can be avoided so knee surgery isn't required^{3,5,30}. Patients experiencing OA have reduced PKFA at stance leading to a quadriceps avoidance gait that is seen in post-operative TKA patients⁵. In order to treat the progression of OA, surgical interventions are recommended¹⁴.

Total Knee Arthroplasty

Most TKA surgeries are carried out on patients as a result of moderate to severe knee osteoarthritis (OA) with the most common location of OA in the medial knee joint compartment to restore joint function and eliminate disabling pain^{8,26}. Most TKA patients are left with high satisfaction¹⁰ at one-year follow-up^{9,11,13,26} according to the Oxford knee score¹¹. However, patient satisfaction and knee function are not correlated, with patients experiencing deficits with activities of daily living^{19,28}.

Van Overschelde et al.¹⁰ assessed patient satisfaction in 250 Total Knee Replacements at two-months following surgery using range of motion, radiographs, and knee injury and osteoarthritis outcome scores. Patients were discharged on the third post-operative day with the majority leaving without walking assistance. At two months post-op 94.6% of patients were satisfied with their implant having mean ROM of 125°. Radiographs showed no loosening or osteolysis in any subjects. They concluded that TKA patients were overall satisfied with their implant. However further studies need to be done to determine if the positive trend in satisfaction continues with time post-operatively.

Total Knee Arthroplasty (TKA) has proven to be successful with having improvement in pain and function and low revision rates, but continues to have high patient dissatisfaction rates. Scott et al.¹¹ evaluated the correlation amongst Passive ROM, and pre- and post-operative pain

and function in 1141 TKA patients (698 women, $\Delta 70.1$ years) at 6 and 12 months following surgery. Follow-up consisted of a Short Form-12 health questionnaire and Oxford Knee Score. Univariate analysis, Spearman's rank correlation, chi-squared test, and multiple ordinate logistic regression were used for statistical analysis. They found there was no statistical difference amongst the 3 types of implants utilized in this study, with 81.4% patient satisfaction (18.6% dissatisfied). Scott et al.¹¹ concluded that a low SF-12 mental component score and pain in other joints were the only pre-operative factors consistent with patient dissatisfaction following surgery.

Noble et al.²⁶ determined which factors contribute to patient satisfaction with TKA and to classify predictors of patient satisfaction and dissatisfaction in 253 TKA unilateral patients (148 women, mean age 67.5 years, and 105 men, mean age 69 years). A Total Knee Function Questionnaire about function and level of satisfaction after surgery was utilized. An analysis of variance, an unpaired t-test was used for data analysis. Seventy-five percent of patients were satisfied and 14% were dissatisfied at one-year follow-up. Ninety-six percent of patients under 60 years of age reported satisfied with their implant, whereas 60-75 year olds reported 81% satisfaction, and more than 75 year olds reported 86% satisfaction. Dissatisfied patients were more likely than satisfied patients to take pain medications once or more per day and reported swelling and stiffness within their knee. Additionally, 50% of dissatisfied patients said they were not as active as they should be, and reported more difficulty and functional deficit than satisfied patients in performing functional activities of greatest importance to them. Overall, patients were satisfied with TKA and those that weren't satisfied need pre-operative concepts of the implant to be improved.

Total Knee Arthroplasty in the younger population has previously been discouraged due to the nature of the surgery. Recently TKA has been offered as an option to provide pain relief and function in the active younger patient with knee OA. Gioe et al.³¹ performed a prospective study on 959 TKA patients (mean age 49.8 years) from the HealthEast Joint Registry to demonstrate the results that can be expected from arthroplasty in patients under 55 years of age (mean follow up of 55 months). Gioe et al.³¹ hypothesized that cemented TKA would have superior survival over other implant designs when considering pre-operative diagnosis, age, gender and cruciate ligament status. Kaplan-Meier survival function, log-rank test, and Cox proportional hazard regression were used for statistical analysis. Revision to the arthroplasty was defined as removal, exchange, or addition of prosthetic component and marked as endpoint for the study. Seventy-three participants had revisions resulting from aseptic loosening, wear/osteolysis, and progression of arthritis in unresurfaced compartments. Gioe et al.³¹ found the TKA implant to have a survival rate of 74.5% at 14 years post-op. They concluded that TKA has an acceptable survival route.

Berchuck et al.²⁸ showed that 75% of anterior cruciate ligament (ACL) deficient patients have an extensional moment pattern called quad avoidance gait, similar to TKA patients. In the absence of the function of the ACL, a patient may subconsciously avoid contracting the quadriceps to avoid displacing the tibia anteriorly. Sixteen patients (14 men) with an unilateral ACL tear and 10 healthy controls (5 men) were taken through level walking, jogging, ascending and descending stair gait analysis. A student t-test was used for statistical analysis. A normal knee flexes 0-20° between foot strike and mid stance of gait. Patients lacking an ACL lacked large external flexion moment and instead had an external extension moment where the hamstrings contract in midstance (quad avoidance gait). They concluded that patients with a

cruciate deficient knee modify their gait, and have similar to function with TKA patients who lack cruciate ligaments.

Chassin et al.¹⁹ determined whether the retention of the ACL in UKA avoids the development of gait adaptations seen in TKA, since the ACL is not preserved in TKA, in 10 patients (7 men, mean age 70 yrs) at an average of 19 months post-operative at normal, slow and fast walking speeds bilaterally. Post-operative radiographs were used to determine limb alignment, as well as a two camera optoelectronic digitizer system at a frequency of 60 Hz for gait analysis. A forceplate was implanted in the ground halfway along a 10 meter walk way. Four of the 10 patients had more than 3° of residual varus alignment which was indicative of increase adduction moment. Seventy percent of UKA patients maintained normal biphasic pattern flexion/extension moments, compared to only 23% of TKA patients. The UKA patients that exhibited quad avoidance gait had patellofemoral symptoms in the non-operated knee. A limitation to this study is that data was only collected on level gait. Stair data would be beneficial in determining if quad avoidance gait is present with that action. Chassin et al. (1996) determined that retention of the ACL in UKA provides an explanation for the difference in gait between UKA and TKA populations.

Though the TKA implant shows a relatively good survival rate that does not correlate with high patient function¹¹. TKA walked with less knee flexion¹³ on level ground as well as with contact ascending stairs, having decreased knee extensor moment and force generation^{8,9} and lower knee extensor muscle strength¹². This is indicative of quad avoidance gait, in which the hamstrings take over to create an internal flexion moment, instead of an internal extension moment by the knee extensors in midstance²⁸. These biomechanical dysfunctions lead to difficulties in performing activities of daily life¹³. Additionally, survivorship of the TKA

implant in younger patients has a lower survival rate at 74.5% compared to 93% survivorship with the UKA implant^{16,31}.

Unilateral Knee Arthroplasty

Unilateral Knee Arthroplasty is indicated similarly for TKA, except OA is limited to the anteromedial compartment of the knee, intact anterior cruciate ligament and collateral ligaments, as well as preserved posterior knee compartments¹⁴. Retrospective studies find that UKA leaves patients with good survivorship and excellent function 1-year to 10-years post operatively^{14,20,32}. Pre- and post-operative range of motion measurements, radiographs^{14,16,32} and the American Knee Society Score were utilized to assess the survivorship of the UKA implant^{16,32}.

Emerson et al.¹⁴ performed a single surgeon retrospective study based on prospectively collected data on primary UKAs using Phase III Mobile-Bearing Oxford Knee. They determined the ten year survivorship of the UKA implant and patient reported outcomes in 173 patients, 213 knees (95 men). Follow up occurred at 6 weeks, 6 months 1 year, and every 2 years after the first post-operative year, consisting of the American Knee Society Score (AKSS), anteroposterior and lateral radiographs, and range of motion (ROM) assessment. A lifetable method for various definitions of failure was utilized for statistical analysis. A revision was defined as any replacement of implant components. Results of 10-year survivorship of UKA was 88%, with only 20 of the knees in this study being revised at a mean age of 6.2 years post-operatively. Revisions were made to the implant to a TKA design as a result of progression to lateral compartment osteoarthritis. In conclusion Emerson et al.¹⁴ found UKA had good survivorship and excellent function 10 years post-op.

Unilateral Knee Arthroplasty has grown in popularity because of its minimally invasive surgical technique. Lisowski et al.³² performed an independent prospective study on 81 UKA

knees (75 patients) at 6-weeks, 6-months, 2-, 5-, 10-, and 15-years post-operatively, to demonstrate the effectiveness and safety of the UKA minimally invasive surgical technique. Post-operative range of motion, stability testing, radiographs, Visual Analog Scale, Knee Society Score, Oxford Knee Score and Western Ontario and McMaster Universities Arthritis Index for pain and satisfaction were utilized. Revision was defined as any surgical procedure that resulted in the removal or exchange of any of the arthroplasty components. They found 77% of knees had good or excellent clinical outcome scores according to the Knee Society Score, and survival of the implant at 15 years was 90.6%. A total of 11 knees underwent revision surgery. Lisowski et al.³² concluded that the Oxford III implant has high survival rate with good to excellent outcome scores, and patients return to functional recovery at 1-year after surgery, proving to be a reliable implant.

The Phase III Oxford Knee Implant is relatively common in the elderly population, but recently has become a surgical alternative for younger individuals. Faour Martin et al.¹⁶ reviewed the long term results of the Oxford UKA implant in 51 patients (59 knees) under the age of 59 years, at an average follow up of 11.87 years through ROM, radiographs and the American Knee Society Score. T-test of comparison of means for paired data was used for statistical analysis. Fifty-five of the knees had not had implant revision at time of follow-up. Pre-operative average knee flexion was 104.5° and post-operative increased to 134.1°. Ninety-one percent of patients were satisfied with the implant, with 27.5% of patients continuing with normal sporting activity.

Kort et al.¹⁵ performed a prospective study to evaluate the mid-term results of the Oxford Phase III Unicompartmental knee replacement in 43 patients (29 women, 46 knees) aged 60 years (mean age 56 yrs) and younger by 4 independent surgeons. Follow-up occurred two to six

years following surgery, consisting of the Knee Society Score (KSS), SF-36 Questionnaire, WOMAC score, and radiographs. Independent t-tests were used for statistical analysis. One hundred percent of the patients that did not undergo revisions had good or excellent KSS. Range of motion increased from 120° pre-operatively to 125° at final follow-up. Two knees were revised to TKA as a result of malalignment of the femoral component and loosening of the tibial component. Revisions occurred in patients that had a BMI greater than 33. Kort et al.¹⁵ concluded that in younger patients UKA is an effective treatment for osteoarthritis yielding successful results, and the contraindication for UKA is a BMI greater than 33.

Naal et al.²⁰ assessed the return to activity rate to detailed and recreational sports in 83 UKA patients (45 men, 65.5±9.1 yrs old). A sport was defined as a physical activity carried out with a recreational or competitive purpose for self-enjoyment to increase or maintain physical fitness and/or attain excellence for the development of skill. Patients participated in 6-week, 3-month, 12-month and yearly follow-up thereafter surgery, completing a sports and activity questionnaire and SF-36. Mann-Whitney U Test, Wilcoxon Signed Rank Test, and Spearman's correlation coefficient were used for statistical analysis. Average follow-up was 18±4.6 months with 94.8% of participants having return to activity from a pre-operative participation in sports of 92.8%. Additionally, participants engaged in activity for the same frequency a week as pre-operatively. Forty-five percent of participants resumed activity 3 months following surgery. High impact activities such as jogging, tennis, soccer and mountain climbing did experience a decrease in activity. Naal et al.²⁰ concluded that UKA offers a good functional return to physical activity with 82% of participants having good or excellent surgical outcomes.

Unilateral knee arthroplasty implant survivorship in retrospective studies yields rates greater than 88% with revisions made to TKA implants due to the progression of OA to the

lateral knee compartment^{14,20,32}. Additionally, UKA implants are implemented in younger patients yielding high implant success rate and leaving patients able to continue with normal sporting activities^{15,16}. UKA patients are able to return to functional recovery 1-year following surgery, while TKA patients are still left with deficits in ROM and daily function³². The UKA knee implant is a favorable implant that more surgeons are relying on to treat knee OA¹⁵.

Walking Gait: TKA v. UKA

The gait pattern for TKA following surgery may be characterized by a shorter stride length, reduction in knee flexion angle during stance, and abnormal patterns of flexion/extension knee moments²³. Studies that compare TKA patients to healthy age-matched controls find that those with the TKA implants have decreased knee and hip flexion angles, decreased knee extension moment, and low force development by the knee extensor muscles⁹. UKA implants are more efficiently able to increase walking speed and have similar knee kinematics to the non-implant limb²³. UKA offers a more functional recovery with early return to work and sporting activities¹⁷.

Total Knee Arthroplasty (TKA) is the most widely used treatment for restoring knee function in patients with end stage OA. Li et al.⁹ quantified the differences in muscle function during walking between 14 TKA patients (67±7 years) and 14 healthy aged matched controls, 12 months following surgery. Motion analysis capture was utilized. Two-way and One-way analysis of variance were utilized for statistical analysis. Total Knee Arthroplasty patients walked with smaller knee flexion and hip flexion angles, had less net knee extension moment, and lower force development from the quadriceps when compared to controls. Peak knee flexion in early stance was 9.7° and 16.2° and knee flexion moment was 14.5 ± 22.5 and 43.5 ± 22.0, for TKA and controls respectively. Li et al.⁹ concluded that by walking with reduced knee flexion

the TKA patients were able to reduce the external moment created by GRF about the knee, thus lower the demand on the quadriceps to generate a resistive knee extension moment.

However, there is research lacking in the patterns exhibited in UKA following surgery, therefore Webster et al.²³ conducted research to characterize foot step pattern and knee kinematics in patients in 12 UKA patients at both selected and maximum walking speeds and were compared to three healthy controls (1 male). Spatial and temporal gait parameters were measured with an electronic mat. Kinematic data was collected with a 6 camera system at a frequency of 50 Hz with Vicon 512 three dimensional analysis system. Paired t-tests were used for statistical analysis. Webster et al. (2003) concluded that UKA participants were able to increase velocity by 28% when required to walk at a fast pace as a result of increasing cadence by 17% and stride length by 11%. There was no significant difference between treated and contralateral limbs for single limb support time as patients walked with notable symmetry at both comfortable and fast walking speeds. Eleven of the 12 participants showed a biphasic flexion/extension about the treated knee during stance, meaning that they did not have quad avoidance gait as often seen with TKA patients¹⁹. At a self-selected speed average flexion-extension ROM was decreased in the implant limb when compared to the healthy limb, similar to the average ROM in controls. In conclusion spatiotemporal patterns were within normal limits and UKA patients had the ability to increase their speed by increasing stride length and cadence, having walking patterns different than TKA following surgery²³.

Braito et al.²¹ performed a prospective comparative study design to compare gait characteristics and knee extensor strength after UKA and TKA surgical procedures pre-operative and 8-weeks post-operative using Vicon 3D motion analysis and an isokinetic dynamometer. Previous research failed to compare UKA procedures to TKA or control groups. Researchers

hypothesized that there would be significant differences in knee extensor strength and gait analysis parameters including, temporospatial patterns, ground reaction force (GRF), knee kinematics and knee kinetics. A multivariate analysis of variance was applied with Hotelling-Spur statistics to analyze significance. Pre-operatively peak extensor torque for UKA and TKA participants was 56.46 Nm and 52.75 Nm respectively. Eight weeks following surgery measurements were 41.13 Nm and 39.6 Nm respectively. No difference was seen between the surgical groups at 8-weeks post-op with regard to any functional outcome parameters. Braito et al.²¹ concluded that there was no significant difference between UKA and TKA surgeries.

Jones et al.²² utilized a machine learning approach to distinguish the differences in gait of 12 matched UKA and TKA patients to 121 healthy controls using Oxford Knee Scores and gait analysis parameters on a treadmill embedded with force plates. It was hypothesized that healthy controls would be more normally classified to UKA's than TKA's due to the joint preserving nature of UKA. Patients walked at a self-selected speed for 6 minutes, after which the treadmill was increased at 0.5 km/h until maximum walking speed was reached. Temporospatial gait parameters and vertical GRF was captured for 10 sec at each speed with a sampling frequency of 100 Hz. Paired t-test or one-way variance with Tukey post hoc analysis and Kendall's W was used for statistical analysis. They found UKA to have a more similar top average walking speed to healthy controls at 2.2 m/s (1.8-2.7) and 2.2 m/s (1.5-2.7) respectively. Top walking speed for TKA was lower at 1.6 m/s (1.3-2.1). Ninety-two percent of healthy controls were determined by the decision tree as medial UKA, supporting the theory that preservation of both cruciate ligaments and unaffected lateral tibiofemoral and patellofemoral compartments of the knee result in a more physiological gait than TKA. Additionally, UKA had faster weight acceptance rate

and higher first peak force, when analyzing initial heel strike, similar to controls. They concluded that UKA enables patients to have more normal gait control than TKA.

Lombardi et al.¹⁷ determined how UKA compares with TKA in terms of durability, incidence of complications and manipulations, postoperative clinical function and return to sport and work, in 103 UKA patients (115 knees) and 596 TKA patients (735 knees) with the Oxford Phase III mobile bearing unicompartmental implant and Vangaurd cruciate retaining prosthesis respectively. Average follow up was 31 months. Clinical outcomes were evaluated with the Knee Society clinical rating system and Lower Extremity Activity Scale, as well as the Oxford Knee Score. Non-paired two-tailed t test and Pearson's Chi-square test were used for statistical analysis. Seven UKA were revised due to tibial fracture, tibial loosening or sepsis, and 3 TKA were revised due to instability. Need for manipulation to regain ROM was greater in TKA (7 patients) than UKA (0 patients). Hospital stays were shorter for UKA than TKA at 1.4 and 2.2 days, respectively. Range of motion at discharge for UKA was 77° compared to 67° for TKA, and at 6-weeks post-operative was 115° for UKA and 110° for TKA. UKA were able to walk longer and had less admission to a skilled nursing facility compared to TKA. Rates of revision however was higher for UKA (6%) than for TKA (3%). They concluded that the UKA implant had acceptable survivorship and outstanding function for the treatment of anteromedial OA, and offers a faster return to a more functional level.

When comparing UKA and TKA gait analysis studies find that at 8-weeks post operatively there is no difference in kinematic variables²¹. Contradictory to those finding, Jones et al. found that UKA are able to elicit more gait control than TKA patients yielding a more physiological gait²². The deficits found in TKA gait can affect their activities of daily life and

make tasks like ascending stairs more challenging⁹. More research needs to be done to explore the deficits between UKA and TKA implants.

Stair Ascent: TKA v. UKA

Functional return following UKA and TKA operations is of high importance with stair ascent being prime due to the increased demand on lower extremity muscle and joints⁸. Researchers compared TKA to healthy controls with stairs, showing the TKA limb in stance has less knee flexion angles and internal knee extension moments than the control limbs^{8,9,12,13}. Not all TKA limbs are able to regain functional ability post-operatively¹³. When comparing UKA limbs to control limbs patients regain functional ability and have more similar knee moments to controls^{24,25}.

Standifird et al.⁸ compared lower-limb biomechanics of 13 TKA replaced joints to the non-replaced limb and 15 healthy controls with stair ascent. They hypothesized that sagittal plane knee variables will be similar in the replaced limb but both would be different when compared to a control limb. Participants completed the 2012 Knee Society Survey to assess recovery following arthroplasty surgery, and the Physical Activity Readiness Survey (PAR-Q) to assess cardiovascular risks to exercise. Participants wore a standardized laboratory running shoe and ascended a 3-step staircase affixed with 2 force plates where visual 3D biomechanical analysis software computed 3D kinematic and kinetic variables. Mixed model analysis of variance, post hoc comparisons with Bonferroni adjustments and independent sample t-tests were used for statistical analysis. Controls had greater passive ROM than both replaced and non-replaced limbs, and non-replaced limbs had greater ROM than replaced limbs. The control limb was more flexed at initial contact at $68.9^{\circ} \pm 4.0$, compared to $65.9^{\circ} \pm 3.5$ of the replaced limb and $65.1^{\circ} \pm 2.7$ in the non-replaced limb. Additionally peak knee extension moment of the control

limb and non-replaced limb was greater than the replaced limb at 0.37 ± 0.27 Nm/kg, 0.35 ± 0.30 Nm/kg, and 0.49 ± 0.33 Nm/kg, respectively. They concluded a stiffer knee contact angle leads to a reduced arm for knee extension causing a deficit in knee extension moment of the replaced knee during the loading response in stair ascent.

Bjerke et al.¹² performed a cross-sectional study on 23 TKA patients and 23 matched controls to analyze possible quadriceps and hamstring weakness in TKA as well as forward trunk lean in stair ascent 1-3 years following surgery. A total of 6 trials (alternating first foot strike) was performed on a 3 step system with 18cm x 26 cm steps. Time for stair ascent was recorded as well as quadriceps and hamstring strength using isokinetic dynamometers. Thirty-four reflective markers with 4-marker clusters on thigh and shank were utilized for gait analysis with an 8 camera system. Kolmogorov-Smirnov statistics were used for analysis. Total Knee Arthroplasty patients ascended stairs at a slower rate when compared to controls, and had 40% less quadriceps strength. Additionally, there was no forward trunk lean by TKA patients to accommodate for muscular weakness. They concluded that compensation for muscle weakness was achieved by ascending stairs at a lower speed. Post-operative improvement in lower extremity strength needs to be achieved to help function in activities of daily life as in ascending stairs.

McClelland et al.¹³ investigated the prevalence of abnormal knee flexion-extension patterns during stair negotiation in 40 TKA patients (22 females, $\Delta 69.1$ years) with 40 matched controls (22 females, $\Delta 69.6$ years), between 12 and 18 months post-operation. An 8-camera Vicon MX3 Motion Analysis System, with a sampling rate of 100Hz was used to collect kinematic data. A 2-step staircase embedded with an elevated force plate was used. Thirteen reflective markers and 4 arrays were used on the thigh and shank. American Knee Society Score

and Total Knee Function Questionnaire were utilized in this study. Step wise discriminant function analysis and hierarchial cluster analysis was used for statistical analysis. Seventy-eight percent of participants were satisfied with their TKA, with 65% of patients not being limited by stair ascent. Twenty participants had an abnormal knee moment pattern, with 6 of those having a knee flexion moment that changed direction to an extension moment during stair ascent. Peak knee flexion moment was significantly reduced compared to controls; 3.8 and 0.3 respectively. Knee flexion angle was lower at 53.4° compared to 60.8° in controls. No significant difference was found between patients that underwent bilateral or unilateral TKA operations. In conclusion not all TKA patients regain functional ability (i.e. stair ascent) similar to healthy controls in age and sex.

Jung et al.¹⁸ compared knee kinematics during stair climbing and level walking in 6 patients (4 women, 65.0 ± 7.5 years) with simultaneous TKA and UKA procedures. Mean UKA follow up was 34.3 ± 11.7 months, and mean follow up for TKA was 41.3 ± 22.2 months. Sixteen retroreflective markers were affixed to the lower extremity and data was collected at a sampling rate of 1000 Hz with Woltring filters for five consecutive successful stair trials. Non-parametric Friedman tests were used for statistical analysis. No significant difference with stance duration was seen between the UKA and TKA limb. Overall UKA and TKA showed similar knee kinematics during stair climbing. UKA limbs however showed greater degrees of rotation freedom which more closely resembles normal knee kinematics with stair climbing, making UKA a viable implant design over TKA.

Fu et al.²⁵ determined if symmetry existed between limbs following 17 medial UKA (68.0 ± 7.4 years, 6 males) and 9 lateral UKA (63.1 ± 7.8 years, 3 males) with stair ascent. Thirty-six reflective markers and VICON motion analysis captured 5 successful stair ascent trials

on each limb. One force plate was embedded in the ground and a second on the first step of the stairs. Woltring's generalized cross-validatory spline was used to smooth raw marker coordinate data. Cardan angles were used to define lower extremity joint angles. A fourth order, low pass Butterworth filter (cutoff frequency of 100 Hz) was applied to GRF and moment signals. Paired t-tests and Pearson's correlations were used for statistical analysis. With the exception of a few participants exhibiting a longer stance and swing phase in the operated limb, there were not significant differences between limbs. Average knee extension in stance phase was 55° and average knee flexion in swing phase was 85°. The UKA implant limb had significantly less peak knee extensor moment than the non-UKA limb at a -0.08 Nm difference. Sagittal plane knee moments showed an eccentric flexion moment during the initial stance phase and then concentric extension moments until 50% of the stance phase. They concluded that there were no differences in sagittal plane knee moment patterns between operated and non-operated limbs, suggesting that UKA yields more similar results to a healthy limb²⁴.

Total Knee and Unilateral Knee Arthroplasties are growing procedures for the treatment of knee osteoarthritis. Total Knee Implants tend to leave patients with more functional deficits than the UKA implant design as can be seen with the ease and difficulties of ascending stairs^{8,12,13,24}. In patients that underwent TKA in one limb and UKA in the contralateral limb, UKA limbs had a greater degree of rotation than the TKA limb¹⁸. Current studies analyze participants post-operatively but lack pre-operative assessments^{8,12,13}. Larger studies need to be performed comparing UKA and TKA function with stair ascent to see if patients improve between their pre-operative and post-operative assessments.

APPENDIX A: TKA CONSENT FORM

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

Biomechanical Comparison of Multi- and Single Radius Implant Designs During Level Walking and Stair Climbing Tasks

PROTOCOL NO.: 2014-018
WIRB® Protocol #20141194

SPONSOR: Cris Stickley, PhD, ATC

INVESTIGATOR: Cass Nakasone, MD
888 South King Street
Honolulu, Hawaii 96813
United States

SITE(S): University of Hawaii at Manoa
PE/A Complex Room 231, Lower Campus Road
Honolulu, Hawaii 96822
United States

Straub Clinic & Hospital
888 S. King Street
Honolulu, Hawaii 96813
United States

STUDY-RELATED

PHONE NUMBER(S): Cass Nakasone, M.D.
808-522-4232

Cris Stickley PhD, ATC
808-956-3798

This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

SUMMARY

You are being asked to be in a research study. The purpose of this consent form is to help you decide if you want to be in the research study. Please read this consent form carefully. To be in a research study you must give your informed consent. "Informed consent" includes:

- Reading this consent form
- Having the study doctor or study staff explain the research study to you
- Asking questions about anything that is not clear, and

- Taking home an unsigned copy of this consent form. This gives you time to think about it and to talk to family or friends before you make your decision.

You should not join this research study until all of your questions are answered.

Things to know before deciding to take part in a research study:

- The main goal of a research study is to learn things to help patients in the future.
- The main goal of regular medical care is to help each patient.
- No one can promise that a research study will help you.
- Taking part in a research study is entirely voluntary. No one can make you take part.
- If you decide to take part, you can change your mind later on and withdraw from the research study.
- The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.
- Parts of this study may involve standard medical care. Standard care is the treatment normally given for a certain condition or illness.
- After reading the consent form and having a discussion with the research staff, you should know which parts of the study are experimental (investigational) and which are standard medical care.
- Your medical records may become part of the research record. If that happens, your medical records may be looked at and/or copied by the sponsor of this study and government agencies or other groups associated with the study.

After reading and discussing the information in this consent form you should know:

- Why this research study is being done;
- What will happen during the research;
- Any possible benefits to you;
- The possible risks to you;
- How problems will be treated during the study and after the study is over.

If you take part in this research study, you will be given a copy of this signed and dated consent form.

PURPOSE OF THE STUDY

The purpose of this study is to compare the function of patients, implanted with either a multi-radii or a single radius total knee arthroplasty design, during level walking and stair climbing tasks. You are being asked to participate in this study because you are undergoing total knee arthroplasty. About 100 subjects are expected to participate.

PROCEDURES

If you decide to participate in this study, you will be randomly assigned (by chance) to one of four possible groups and receive either a single radius knee implant or one of three multiple radii

knee implants. You have an equal chance of being assigned to any one of the four implant groups. The implants that will be used in this study are:

- GetAroundKnee™, Stryker Orthopedics (single radius)
- Balanced Knee® System, Ortho Development (multiple radii),
- Persona™ Total Knee, Zimmer (multiple radii)
- NexGen®, Zimmer (multiple radii)

These types of implants are approved by the FDA for the type of surgery you are having and will be used according to their approved indication.

You will be asked to report to the University of Hawaii at Manoa, Kinesiology and Rehabilitation Science Laboratory (Gait Lab) (Sheriff 100) for all testing visits before and after your knee surgery.

Upon arrival to the Gait Lab, you will be asked to fill out one survey in reference to your current pain and activity level. Measurements about your body will be taken and you will be asked to perform the following tasks:

- (1) walk for 6 meters at a comfortable speed 6-10 times (Gait Analysis),
- (2) walking up and down stairs at a comfortable speed 3-4 times, and
- (3) push into stationary objects (fixed dynamometer) with your leg for three seconds for two different leg movements (Isometric Strength).

You will also be asked some questions about your daily activities. The entire visit will take approximately 60 minutes.

You will be asked to go to the Gait Lab for your first study visit before your surgery. You will be asked to return to the Gait Lab 5 more times over the next two years to repeat the procedures listed above (please see Table 1 below for visit schedule). Each visit to the Gait lab will take approximately 60 minutes.

Table 1. Visit Time Line

	Before Surgery	6 Weeks After Surgery	3 Months After Surgery	6 Months After Surgery	1 Year After Surgery	2 Years After Surgery
Gait Analysis (test)	X	X	X	X	X	X
Isometric Strength	X	X	X	X	X	X
Paper/Pencil Survey	X	X	X	X	X	X

RISKS AND DISCOMFORTS

Being randomized to one type of knee implant instead of the others, may lead to greater or lesser stability of the knee post-surgery.

There are risks associated with your knee replacement surgery, whether or not you participate in this study. These include:

- Blood clots that can, in rare cases, be life threatening
- Complications after a blood transfusion
- Allergic reaction to the medications or materials used
- Infection
- Injury to arteries or nerves in your leg
- Surgery may not reduce your pain and stiffness, possibly requiring more treatment
- Surgery may cause more pain
- Risks of anesthesia

You will be asked to review and sign a separate consent form for your knee surgery, and your surgeon will explain the risks of the procedure in more detail.

Gait analysis risks

Due to the level of physical activity involved during the testing procedures, there is a risk of injury. You may have pain in your affected joint during testing. You may also have some discomfort, muscle cramping or soreness during or after test sessions. Although we have people to assist you and handrails in place, there is a chance of falling during the test. There is a very remote chance of cardiac arrest and/or death. These risks are comparable to your routine rehabilitation and activities of daily living, and will not affect your recovery from the surgery.

You cannot participate in this study if you are pregnant because the information collected during the walking test may not accurately represent your normal walking characteristics. If you are unaware that you are pregnant, participation in this study will result in no more danger to the mother or fetus than normal activities of daily living. However, if you become pregnant or think you might be pregnant during the course of this study, you must inform the researchers, and you will be removed from study participation.

NEW INFORMATION

You will be told about anything new that might change your decision to be in this study. You may be asked to sign a revised consent form if this occurs.

BENEFITS

You may not receive direct/immediate benefits from study participation. However, you will obtain information regarding your walking gait, functional activity capacity, hip muscular strength, and behavioral characteristics. Results of this study may assist physicians, physical therapists, and athletic trainers to ensure the optimal clinical outcomes to maintain the beneficial effects of total knee replacement.

PAYMENT FOR PARTICIPATION

You will not be paid for your participation in the study.

You will be given \$5 that can be applied towards parking and/or transportation to the University of Hawaii Gait Laboratory each time you come for a visit. The money will be given to you after you arrive at the facility with a receipt, so it is a reimbursement. You will be reimbursed only for the visits that you attend.

COSTS

You are not expected to have additional costs related to the procedures and visits that may result from your participation in this research study.

Any additional costs associated with parking/transportation over and above the \$5 provided will be your responsibility. The fee for parking at the University of Hawaii parking structure is \$5 during the week and \$6 on the weekends.

ALTERNATIVE TREATMENT

If you decide not to participate in this study, you will receive your knee replacement surgery with the type of implant that your doctor feels is best for you. Your follow-up care will be the same whether or not you are in this study.

USE AND DISCLOSURE OF YOUR HEALTH INFORMATION:

By signing this form you are authorizing the use and disclosure of individually identifiable information. Your information will only be used/disclosed as described in this consent form and as permitted by state and federal laws. If you refuse to give permission, you will not be able to be in this research.

This consent covers all information about you that is used or collected for this study. It includes

- Past and present medical records
- Research records
- Records about your study visits.
- Information gathered for this research about:
 - Physical exams
 - Laboratory, x-ray, and other test results
 - Questionnaires
- Records about the implanted medical device.

Your authorization to use your identifiable health information will not expire even if you terminate your participation in this study or you are removed from this study by the study doctor. However, you may revoke your authorization to use your identifiable information at any time by submitting a written notification to the principal investigator, Cass Nakasone, MD at 888 S. King Street, Honolulu, HI 96813. If you decide to revoke (withdraw or “take back”) your authorization, your identifiable health information collected or created for this study shall not be used or disclosed by the study doctor after the date of receipt of the written revocation except to the extent that the law allows us to continue using your information. The investigators in this study are not required to destroy or retrieve any of your health information that was created, used or disclosed for this study prior to receiving your written revocation.

By signing this consent form you authorize the following parties to use and or disclose your identifiable health information collected or created for this study:

- Cass Nakasone, MD and his research staff for the purposes of conducting this research study.
- Straub Clinic & Hospital and Hawai'i Pacific Health

Your medical records may contain information about AIDS or HIV infection, venereal disease, treatment for alcohol and/or drug abuse, or mental health or psychiatric services. By signing this consent form, you authorize access to this information if it is in the records used by members of the research team.

The individuals named above may disclose your medical records, this consent form and the information about you created by this study to:

- The sponsor of this study and their designees (if applicable)
- Federal, state and local agencies having oversight over this research, such as the Office for Human Research Protections in the U.S. Department of Health and Human Services, Food and Drug Administration, the National Institutes of Health, etc.
- The University of Hawai'i
- Hawaii Pacific Health (HPH) Officials, the Western Institutional Review Board, and the HPH Office of Compliance for purposes of overseeing the research study and making sure that your ethical rights are being protected.

Some of the persons or groups that receive your study information may not be required to comply with federal privacy regulations, and your information may lose its federal privacy protection and your information may be disclosed without your permission.

COMPENSATION FOR INJURY

In the event of any physical injury from the research, only immediate and essential medical treatment is available. First Aid/CPR and a referral to a medical emergency room will be provided. In the event of any emergency incidence outside the lab as a result of this research, contact your regular medical doctor and inform the study coordinator: Cris Stickley Ph.D., ATC, at 808-956-3798. You should understand that, if you are injured in the course of this research process, you or your medical insurance will be billed for the costs of treating your injuries.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent for any of the following reasons:

- it is in your best interest;

- you do not consent to continue in the study after being told of changes in the research that may affect you;
- you become pregnant;
- or for any other reason.

If you leave the study before the planned final visit, you may be asked by the study doctor to have some of the end of study procedures done.

SOURCE OF FUNDING FOR THE STUDY

This research study is sponsored by the University of Hawaii, Manoa.

QUESTIONS

Contact Cris Stickley Ph.D., ATC at 808-956-3798 or Dr. Cass Nakasone at 808-522-4232 for any of the following reasons:

- if you have any questions about this study or your part in it
- if you feel you have had a research-related injury or
- if you have questions, concerns or complaints about the research

If you have questions about your rights as a research subject or if you have questions, concerns, input, or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
 1019 39th Avenue SE Suite 120
 Puyallup, Washington 98374-2115
 Telephone: 1-800-562-4789 or 360-252-2500
 E-mail: Help@wirb.com.

WIRB is a group of people who perform independent review of research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Do not sign this consent form unless you have had a chance to ask questions and have gotten satisfactory answers.

If you agree to be in this study, you will receive a signed and dated copy of this consent form for your records.

CONSENT

I have read this consent form. All my questions about the study and my part in it have been answered. I freely consent to be in this research study.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form, I have not given up any of my legal rights.

Subject Name (printed)

CONSENT SIGNATURE:

Signature of Subject Date

Signature of Person Conducting Informed Consent Discussion Date

APPENDIX B: UKA CONSENT FORM

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

Biomechanical Analysis of the Oxford® Unicompartmental Knee Implant Design During Level Walking and Stair Negotiation

PROTOCOL NO.: 2016-007

SPONSOR: Cris Stickley, PhD, ATC
Honolulu, Hawaii
United States

INVESTIGATOR: Cass Nakasone, M.D.
888 South King Street
Honolulu, Hawaii 96813
United States

STUDY-RELATED

PHONE NUMBER(S): Cass Nakasone, M.D.
808-522-4000

Cris Stickley PhD, ATC
808-956-3798

This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

SUMMARY

You are being asked to be a participant in a research study. The purpose of this consent form is to help you decide if you want to be in the research study. Please read this consent form carefully. To be in a research study you must give your informed consent. “Informed consent” includes:

- Reading this consent form
- Having the study doctor or study staff explain the research study to you
- Asking questions about anything that is not clear, and
- Taking home an unsigned copy of this consent form. This gives you time to think about it and to talk to family or friends before you make your decision.

You should not join this research study until all of your questions are answered.

Things to know before deciding to take part in a research study:

- The main goal of a research study is to learn things to help patients in the future.

- The main goal of regular medical care is to help each patient.
- No one can promise that a research study will help you.
- Taking part in a research study is entirely voluntary. No one can make you take part.
- If you decide to take part, you can change your mind later on and withdraw from the research study.
- The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.
- Parts of this study may involve standard medical care. Standard care is the treatment normally given for a certain condition or illness.
- After reading the consent form and having a discussion with the research staff, you should know which parts of the study are experimental (investigational) and which are standard medical care.
- Your medical records may become part of the research record. If that happens, your medical records may be looked at and/or copied by the sponsor of this study and government agencies or other groups associated with the study.

After reading and discussing the information in this consent form you should know:

- Why this research study is being done;
- What will happen during the research;
- Any possible benefits to you;
- The possible risks to you;
- How problems will be treated during the study and after the study is over.

If you take part in this research study, you will be given a copy of this signed and dated consent form.

PURPOSE OF THE STUDY

The purpose of this study is to compare the function of patients with the Oxford partial knee implant design during level walking and stair negotiation tasks.

Approximately 20 people will participate in this study.

PROCEDURES

If you decide to participate in this study you will be receiving per the physician's protocol the Oxford partial knee implant which is approved by the FDA for the type of surgery you are having and will be used according to their approved indication.

You will be asked to report to the University of Hawaii at Manoa, Kinesiology and Rehabilitation Science Laboratory (Gait Lab) (Sheriff 100) for all testing before and after your knee surgery.

Upon arrival to the Gait Lab, you will be asked to fill out one survey in reference to your current pain and activity level.

When you arrive at the Gait Lab measurements about your body will be taken and you will be asked to perform the following tasks:

- (1) walk for 6 meters at a comfortable speed 6-10 times (Gait Analysis),
- (2) walking up and down stairs at a comfortable speed 3-4 times, and
- (3) push into stationary objects (fixed dynamometer) with your leg for three seconds for two different leg movements (Isometric Strength).

You will also be asked some questions about your daily activities. The entire visit will take approximately 60 minutes.

You will be asked to go to the Gait Lab for your first study visit before your surgery. Each visit to the Gait lab will take approximately 60 minutes. You will be asked to return to the Gait Lab four more times over the next one year to repeat the procedures listed above (please see Table 1 below for visit schedule).

Table 1. Visit Time Line

	Before Surgery	6 Weeks After Surgery	3 Months After Surgery	6 Months After Surgery	1 Year After Surgery
Gait Analysis (test)	X	X	X	X	X
Isometric Strength	X	X	X	X	X
Survey	X	X	X	X	X

RISKS AND DISCOMFORTS

There are risks associated with your knee replacement surgery. These include:

- Blood clots that can, in rare cases, be life threatening
- Complications after a blood transfusion
- Allergic reaction to the medications or materials used
- Injury to arteries in your leg
- Surgery may not reduce your pain and stiffness, possibly requiring more treatment
- Surgery may cause more pain

Due to the level of physical activity involved, there is a risk of injury. You may have pain in your affected joint during testing. You may also have some discomfort, muscle cramping or soreness during or after test sessions. Although we have people to assist you and handrails in place, there is a chance of falling during the test. There is a very remote chance of cardiac arrest and/or death. These risks are comparable to your routine rehabilitation and activities of daily living, and will not affect your recovery from the surgery.

You cannot participate in this study if you are pregnant because the information collected during the walking test may not accurately represent your normal walking characteristics. If you are unaware that you are pregnant, participation in this study will result in no more danger to the mother or fetus than normal activities of daily living. However, if you become pregnant or think you might be pregnant during the course of this study, you must inform the researchers, and you will be excluded from study participation.

NEW INFORMATION

You will be told about anything new that might change your decision to be in this study. You may be asked to sign a revised consent form if this occurs.

BENEFITS

You may not receive direct/immediate benefits. However, you will obtain information regarding your walking gait, functional activity capacity, hip muscular strength, and behavioral characteristics. Results of this study may assist physicians, physical therapists, and athletic trainers to ensure the optimal clinical outcomes to maintain the beneficial effects of knee replacement.

PAYMENT FOR PARTICIPATION

You will be given \$5 that can be applied towards parking and/or transportation to the University of Hawaii Gait Laboratory each time you come for a visit. The money will be given to you after you arrive to the facility so it is a reimbursement. If you do not finish the study, you will be paid only for the visits you have completed.

COSTS

There are no additional costs related to the procedures and visits that may result from your participation in this research study.

Any costs associated with parking/transportation over and above the \$5 provided will be your responsibility. The fee for parking at the University of Hawaii parking structure is \$5 during the week and \$6 on the weekends.

ALTERNATIVE TREATMENT

Your alternative is not to participate in this study.

USE AND DISCLOSURE OF YOUR HEALTH INFORMATION:

By signing this form, you are authorizing the use and disclosure of individually identifiable information. Your information will only be used/disclosed as described in this consent form and as permitted by state and federal laws. If you refuse to give permission, you will not be able to be in this research.

This consent covers all information about you that is used or collected for this study. It includes

- Past and present medical records
- Research records
- Records about your study visits.
- Information gathered for this research about:
 - Physical exams
 - Laboratory, x-ray, and other test results
 - Questionnaires
- Records about the implanted medical device.

Your authorization to use your identifiable health information will not expire even if you terminate your participation in this study or you are removed from this study by the study doctor. However, you may revoke your authorization to use your identifiable information at anytime by submitting a written notification to the principal investigator, Cass Nakasone, MD at 888 S. King Street, Honolulu, HI 96813. If you decide to revoke (withdraw or “take back”) your authorization, your identifiable health information collected or created for this study shall not be used or disclosed by the study doctor after the date of receipt of the written revocation except to the extent that the law allows us to continue using your information. The investigators in this study are not required to destroy or retrieve any of your health information that was created, used or disclosed for this study prior to receiving your written revocation.

By signing this consent form you authorize the following parties to use and or disclose your identifiable health information collected or created for this study:

- Cass Nakasone, MD and his research staff for the purposes of conducting this research study.
- Straub Medical Center and Hawai‘i Pacific Health
- The University of Hawai‘i

Your medical records may contain information about AIDS or HIV infection, venereal disease, treatment for alcohol and/or drug abuse, or mental health or psychiatric services. By signing this consent form, you authorize access to this information if it is in the records used by members of the research team.

The individuals named above may disclose your medical records, this consent form and the information about you created by this study to:

- The sponsor of this study and their designees (if applicable)
- Federal, state and local agencies having oversight over this research, such as the Office for Human Research Protections in the U.S. Department of Health and Human Services, Food and Drug Administration, the National Institutes of Health, etc.
- The University of Hawai‘i
- Hawaii Pacific Health (HPH) Officials, the Western Institutional Review Board, and the HPH Office of Compliance for purposes of overseeing the research study and making sure that your ethical rights are being protected.

Some of the persons or groups that receive your study information may not be required to comply with federal privacy regulations, and your information may lose its federal privacy protection and your information may be disclosed without your permission.

COMPENSATION FOR INJURY

In the event of any physical injury from the research, only immediate and essential medical treatment is available. First Aid/CPR and a referral to a medical emergency room will be provided. In the event of any emergency incidence outside the lab as a result of this research, contact your medical doctor and inform the study coordinator: Cris Stickley Ph.D., ATC, at 808-956-3798. You should understand that if you are injured in the course of this research process that you or your medical insurance will be billed for the costs of treating your injuries.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent for any of the following reasons:

- it is in your best interest;
- you do not consent to continue in the study after being told of changes in the research that may affect you;
- you become pregnant;
- or for any other reason.

If you leave the study before the planned final visit, you may be asked by the study doctor to have some of the end of study procedures done.

SOURCE OF FUNDING FOR THE STUDY

This research study is sponsored by the University of Hawai‘i at Manoa.

QUESTIONS

Contact Cris Stickley Ph.D., ATC at 808-956-3798 or Dr. Cass Nakasone at 808-522-4232 for any of the following reasons:

- if you have any questions about this study or your part in it
- if you feel you have had a research-related injury or
- if you have questions, concerns or complaints about the research

If you have questions about your rights as a research subject or if you have questions, concerns or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)

1019 39th Avenue SE Suite 120
Puyallup, WA 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com.

WIRB is a group of people who perform independent review of research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Do not sign this consent form unless you have had a chance to ask questions and have gotten satisfactory answers.

If you agree to be in this study, you will receive a signed and dated copy of this consent form for your records.

CONSENT

I have read this consent form. All my questions about the study and my part in it have been answered. I freely consent to be in this research study.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form, I have not given up any of my legal rights.

Subject Name (printed)

CONSENT SIGNATURE:

Signature of Subject Date

Signature of Person Conducting Informed Consent Discussion Date

APPENDIX C: CONTROL CONSENT FORM

INFORMED CONSENT **To Participate in a Research Study**

Department of Kinesiology and Rehabilitation Science, University of Hawaii at Manoa
1337 Lower Campus Road, PE/A Complex Rm. 231, Honolulu, HI 96822
Phone: 808-956-7606

I. INVESTIGATORS

Principal Investigators: Cris Stickley, PhD, ATC

Investigators: Elizabeth Parke, MS, ATC

II. TITLE

Biomechanical Analysis of Level Walking and Stair Climbing Tasks Across a Lifespan.

III. INTRODUCTION

The following information is being provided to help you decide if you would like to participate in this study. This form may have words that you do not understand. If you have questions, please ask us. The purpose of this study is to evaluate biomechanical variables during level walking and stair climbing tasks in a healthy control population.

IV. DESCRIPTION OF PROCEDURES

You will be asked to report to the University of Hawaii at Manoa Gait Lab (Sherriff 100) for a one-time data collection. The entire visit will take approximately 60 minutes.

When you arrive at the Gait Lab measurements about your body will be taken and you will be asked to perform the following tasks:

- (1) Complete a health history questionnaire as well as a physical activity questionnaire
- (2) Walk for 6 meters at a various speed multiple times,
- (3) Walk up and down stairs at a comfortable speed 5 times, and
- (4) push into stationary objects (fixed dynamometer) with your leg for three seconds for two different leg movements to measure lower leg strength.

V. RISKS

Due to the physical activity involved, there is a slight risk of injury. You may also have some discomfort, muscle cramping or soreness during or after test sessions. Although we have people to assist you and handrails in place during the stair climbing task, there is a slight chance of falling during the test. There is a very remote chance of cardiac arrest and/or death. These risks are comparable to your routine activities of daily living.

The investigators of this study are NATABOC certified athletic trainers and First Aid/CPR/AED trained. In the event of any physical injury from the research, only immediate and essential medical treatment is available including an AED. First Aid/CPR and a referral to a medical emergency room will be provided. In the event of any emergency incidence outside the lab as a result of this research, contact your medical doctor and inform the principal investigator,

Cris Stickley, PhD, ATC, at 513-259-4666 or Elizabeth Parke, MS, ATC at 336-402-3816. You should understand that if you are injured in the course of this research process that you alone will be responsible for the costs of treating your injuries.

You cannot participate in this study if you are pregnant because the information collected during the walking test may not accurately represent your normal walking characteristics. If you are unaware that you are pregnant, participation in this study will result in no more danger to the mother or fetus than normal activities of daily living. However, if you think you might be pregnant during the course of this data collection, you must inform the researchers, and you will be excluded from study participation.

VI. BENEFITS

You may not receive direct/immediate benefits. However, you will obtain information regarding your walking and running gait upon requests.

VII. COMPENSATION

No compensation will be given to patients throughout this study, however, a parking fee of five dollars will be reimbursed when the patients arrives at data collection with a receipt. Reimbursement will only be given to for data collections the patient is present.

VIII. CONFIDENTIALITY

Your research records will be confidential to the extent permitted by law. Agencies with research oversight, such as The University of Hawaii Committee on Human Studies, have the right to review research records.

An identification number will be used to identify you during the study, which will be known only to you and study personnel. In addition, all data and subject (identity) information will be kept under lock and key in the Department of Kinesiology and Rehabilitation Science at the University of Hawaii at Manoa. These materials will be permanently disposed of in a period not longer than 5 years. You will not be personally identified in any publication arising from this study. Personal information about your test results will not be given to anyone without your written permission.

IX. CERTIFICATION

I certify that I have read and I understand the foregoing, that I have been given satisfactory answers to my inquiries concerning the project procedures and other matters and that I have been advised that I am free to withdraw my consent participation and to discontinue participation in the project or activity at any time without prejudice.

I herewith consent to participate in this project with the understanding that such consent does not waive any of my legal rights, nor does it release the principal investigator or institution or any employee or agent thereof from liability for negligence.

I attest that I am not currently limited from full participation in my chosen sport due to injury.

I attest that I do not believe that I am currently pregnant.

If you have any questions related to this study, please contact any of the principal investigators: Cris Stickley at 513-259-4666 or Elizabeth Parke, MS, ATC, at 336-402-3816 at any time.

Participant's Printed Name

Signature of Participant

Date

Witness Signature

Date

If you cannot obtain satisfactory answers to your questions, or have complaints about your treatment in this study, please contact: Committee on Human Subjects, University of Hawai'i at Manoa, **1960 East-West Rd., Biomed Bldg. Ste. B-104**, Honolulu, Hawaii 96822, Phone (808) 956-5007.

APPENDIX D: DATA COLLECTION FORMS

Activity Assessment Survey

Subject ID#: _____ Data Collection Period 0 1 2 3 4 5 6 7

Please circle the number that best describes current activity level.

1. Wholly inactive, dependent on others, and can not leave residence
2. Mostly inactive or restricted to minimum activities of daily living
3. Sometimes participates in mild activities, such as walking, limited housework and limited shopping
4. Regularly participates in mild activities
5. Sometimes participates in moderate activities such as swimming or could do unlimited housework or shopping
6. Regularly participates in moderate activities
7. Regularly participates in active events such as bicycling
8. Regularly participates in active events, such as golf or bowling
9. Sometimes participates in impact sports such as jogging, tennis, skiing, acrobatics, ballet, heavy labor or backpacking
10. Regularly participates in impact sports

Please circle the number that best answers the following question. "How does your knee affect your ability to rise from a chair?":

1. "Because of my knee I cannot rise from a chair."
2. "Because of my knee, I can only rise from a chair if I use my hands and arms to assist."
3. "I have pain when rising from the seated position, but it does not affect my ability to rise from the seated position."
4. "My knee does not affect my ability to rise from a chair."

Are you satisfied with your implant?
Yes No

Anthropometric Data

Subject ID#: _____ Date _____

Age _____ Gender: F / M

Data Collection Period 0 1 2 3 4 5

Patient's Operated leg: L / R Dominant Leg: L / R

Date of Surgery _____

Weeks after Surgery _____

Vicon/Nexus Measurements

Weight (kg)	
Height (mm)	
Age (yrs)	
Left leg length (mm)	
Left knee width (mm)	
Left ankle width (mm)	
Right leg length (mm)	
Right knee width (mm)	
Right ankle width (mm)	

Data Collection Form

Subject ID#: _____

Data Collection Period 0 1 2 3 4 5

Patient's Operated leg: L / R

Dominant leg: L / R

Total Trials: 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20

Walking Trials		
Trial	Which foot hit the plate	Walking Pace (s)
1	R / L	
2	R / L	
3	R / L	

Stair Ascent		
Trial	Which foot hit the plate	Walking Pace (s)
1	R / L	
2	R / L	
3	R / L	

Stair Decent		
Trial	Which foot hit the plate	Walking Pace (s)
1	R / L	
2	R / L	
3	R / L	

Manual Muscle Testing Data Collection

Subject ID#: _____ Data Collection

Period 0 1 2 3 4 5 6 7

Patient's Operated leg: L / R

Dominant Leg: L / R

Tester: _____

	Left Leg						Right Leg					
	Trial 1 Score (ft-lb.)	Pain Score (HHD /Jt)	Trial 2 Score (ft-lb.)	Pain Score (HHD /Jt)	Trial 3 Score (ft-lb.)	Pain Score (HHD /Jt)	Trial 1 Score (ft-lb.)	Pain Score (HHD /Jt)	Trial 2 Score (ft-lb.)	Pain Score (HHD /Jt)	Trial 3 Score (ft-lb.)	Pain Score (HHD /Jt)
Hip abduction		/		/		/		/		/		/
Knee extension		/		/		/		/		/		/

APPENDIX E: CONTROL PARTICIPANT HEALTH QUESTIONNAIRE



ID #: _____ DATE: _____

Participant Health Questionnaire:			
1	Has your doctor ever said that you have a heart condition and that you should only perform physical activity recommended by a doctor?	YES	NO
2	In the past month, have you had chest pain?	YES	NO
3	Do you lose your balance because of dizziness?	YES	NO
4	Have you ever been diagnosed with Parkinson's Disease?	YES	NO
5	Do you have a history of fainting?	YES	NO
6	Have you ever been diagnosed with a neurological disorder?	YES	NO
7	Do you have diabetes mellitus?	YES	NO
8	Do you have a bone or joint problem that could be made worse by physical activity?	YES	NO
9	Has a doctor ever diagnosed you with rheumatoid arthritis or osteoarthritis?	YES	NO
10	Within the six months, have you experienced an injury to your knee or any severe knee pain?	YES	NO
11	Have you had a previous hip, knee, ankle or foot surgery?	YES	NO

M / F _____ AGE: _____

ANTHROPOMETRICS
(to be filled out by the research team)

WEIGHT: _____ **HEIGHT:** _____

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